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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/421,213 | 10/20/99 | O'DRIEN | |

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HM22/0713

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| EXAMINER HARRISON |
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| ART UNIT 42 | PAPER NUMBER |
|-------------|--------------|

10/13/01

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/421,213

Applicant(s)

O'Brien And Tanlomot

Examiner
Alana M. Harris, Ph. D.

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on March 13, 2001.

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above, claim(s) 1-21 and 25-52 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 22-24 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12

20) ☐ Other:

Art Unit: 1642

DETAILED ACTION

Response to Amendment

1. Claims 1-52 are pending.

Claims 1-21 and 25-52, drawn to non-elected inventions are withdrawn from examination.

Claims 22 and 24 have been amended.

Claims 22-24 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

3. The Examiner acknowledges that a new combined declaration has been submitted that includes the inventors' signatures.

Drawings

4. The Examiner acknowledges the drawings have been amended and that formal drawings will be submitted upon acceptance of the instant application.

Art Unit: 1642

Specification

5. The abstract does reference the claimed invention in the instant application and no longer objected.

6. The title of the invention is no longer objected due to the fact it reflects the instant invention.

7. The disclosure is no longer objected to because of the figures no longer reference Figure 12-1 and Figure 12-2, hence there is no need to reference them in the Description of Figures.

Withdrawn Rejections

Claim Rejections - 35 U.S.C. § 112

8. The rejection of claims 22-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants' amendments to the claims.

Art Unit: 1642

Maintained Rejections

Claim Rejections - 35 U.S.C. § 103

9. The rejection of claims 22-24 under 35 U.S.C. 103(a) as being unpatentable over Accession #W22987 (October 8, 1997), in view of Lerner (Nature 299:592-596, 1982) is maintained.

Applicants' argue that "[c]laims 22 and 24 explicitly state that the antibody in the kit is 'specific for TADG-15'" and [a]n antibody raised against W22987 would not fit this criterion." Applicants also argue that TADG-15 is 100% identical to another protease that starts after residue 615 and it would be obvious that an antibody specific for TADG-15 must be generated from amino acid sequences before 615. This is found unpersuasive.

The term "specific" is not the same as exclusive, hence it is within the purview of the Examiner that an antibody raised against W22987 would fit the criterion listed in Applicants claims. Applicants' arguments are directed to limitations not listed in the claims. Applicants are cautioned against the addition of new matter. If amendments to the recited claims are made in order to clarify, Applicants should identify the page and lines to which support for amendments can be found.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1642

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
July 9, 2001

Sheela G Huff
SHEELA HUFF
PRIMARY EXAMINER